

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

INFOSINT S.A.,

Plaintiff,

v.

FOREST PHARMACEUTICALS, INC.

Defendant.

Civil Action No. 07 CIV 6525

DEFENDANT'S ANSWER AND COUNTERCLAIMS

DEMAND FOR JURY TRIAL

Defendant Forest Pharmaceuticals, Inc. ("Forest Pharma") for its Answer and Counterclaims to the Complaint of Plaintiff Infosint S.A. ("Infosint"), hereby states as follows:

COMPLAINT PARAGRAPH 1

Infosint is a Swiss corporation having a principal place of business at Via Cantonale 658a, P.O. Box 83, CH-7745 Poschiavo, Li Curt, Switzerland.

ANSWER TO COMPLAINT PARAGRAPH 1

On information and belief, Defendant admits the averments contained in Complaint Paragraph 1.

COMPLAINT PARAGRAPH 2

On information and belief, Forest Pharma is a Delaware corporation, having a principal place of business at 13600 Shoreline Drive, Earth City, Missouri. On information and belief, Forest Pharma sells pharmaceutical products containing citalopram manufactured by H. Lundbeck A/S in the United States under the trademarks CELEXATM and LEXAPROTM.

ANSWER TO COMPLAINT PARAGRAPH 2

Defendant admits that Forest Pharma is a Delaware corporation, having a principal place of business at 13600 Shoreline Drive, Earth City, Missouri. Defendant further admits that Forest Pharma sells pharmaceutical products in the United States containing citalopram or escitalopram made outside the United States by H. Lundbeck A/S under the trademarks CELEXA[®] or LEXAPRO[®] respectively. Defendant denies the remaining averments contained in Complaint Paragraph 2.

COMPLAINT PARAGRAPH 3

This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq. Subject matter jurisdiction exists by virtue of 28 U.S.C. §§ 1331 and 1338(a).

ANSWER TO COMPLAINT PARAGRAPH 3

Defendant admits that this action purports to arise under the patent laws of the United States, 35 U.S.C. §1 *et seq.* Defendant further admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Defendant, however, denies that there is any factual or legal basis for any of Infosint's claims in this action.

COMPLAINT PARAGRAPH 4

On October 1, 2002, U.S. Patent No. 6,458,973 ("the '973 patent"), entitled "Process for the Preparation of 5-Carboxyphthalide," was duly and legally issued by the United States Patent and Trademark Office. A copy of the '973 patent is attached as Exhibit A.

ANSWER TO COMPLAINT PARAGRAPH 4

Defendant admits that the '973 patent, titled "Process for the Preparation of 5-Carboxyphthalide," issued on October 1, 2002 and that a copy of the '973 patent was attached to Infosint's Complaint as Exhibit A. Defendant, however, denies that the '973 patent was duly and

legally issued. To the extent that Complaint Paragraph 4 contains any other or different averments, Defendant denies them.

COMPLAINT PARAGRAPH 5

On March 9, 2004, U.S. Patent No. 6,703,516 ("the '516 patent"), entitled "Process for the Preparation of 5-Carboxyphthalide," was duly and legally issued by the United States Patent and Trademark Office. A copy of the '516 patent is attached as Exhibit B.

ANSWER TO COMPLAINT PARAGRAPH 5

Defendant admits that the '516 patent, titled "Process for the Preparation of 5-Carboxyphthalide," issued on March 9, 2004 and that a copy of the '516 patent was attached to Infosint's Complaint as Exhibit B. Defendant, however, denies that the '516 patent was duly and legally issued. To the extent that Complaint Paragraph 5 contains any other or different averments, Defendant denies them.

COMPLAINT PARAGRAPH 6

Infosint is the owner of the entire right, title and interest in the '973 patent through assignment from Norpharma S.p.A. to Infosint effective October 2002.

ANSWER TO COMPLAINT PARAGRAPH 6

Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments contained in Complaint Paragraph 6 and, on that basis, denies them.

COMPLAINT PARAGRAPH 7

Infosint is the owner of the entire right, title and interest in the '516 patent.

ANSWER TO COMPLAINT PARAGRAPH 7

Defendant is without knowledge or information sufficient to form a belief as to the truth of the averments contained in Complaint Paragraph 7 and, on that basis, denies them.

COMPLAINT PARAGRAPH 8

The '973 and '516 patents claim improved processes for preparation of the antidepressant citalopram, which include an improved process for the preparation of 5-carboxyphthalide.

ANSWER TO COMPLAINT PARAGRAPH 8

Defendant admits that the '973 and '516 patents contain claims to processes for the preparation of 5-carboxyphthalide. Defendant denies the remaining averments contained in Complaint Paragraph 8.

COMPLAINT PARAGRAPH 9

On information and belief, the citalopram products imported into and/or sold within the United States by Forest Pharma are manufactured outside the United States by H. Lundbeck A/S using a process claimed in the '973 patent.

ANSWER TO COMPLAINT PARAGRAPH 9

Denied

COMPLAINT PARAGRAPH 10

On information and belief, the citalopram products imported into and/or sold within the United States by Forest Pharma are manufactured outside the United States by H. Lundbeck A/S using a process claimed in the '516 patent.

ANSWER TO COMPLAINT PARAGRAPH 10

Denied.

COMPLAINT PARAGRAPH 11

Each of the preceding paragraphs 1 through 10 above, inclusive, is incorporated herein by reference.

ANSWER TO COMPLAINT PARAGRAPH 11

Defendant restates and incorporates by reference its responses to the averments contained in Complaint Paragraphs 1 through 10 as though fully set forth herein.

COMPLAINT PARAGRAPH 12

Defendant Forest Pharma has imported and is importing into the United States and/or has offered to sell, sold, or used and is offering to sell, selling and using within the United States, citalopram made by a process covered by one or more of the claims of the '973 patent.

ANSWER TO COMPLAINT PARAGRAPH 12

Denied

COMPLAINT PARAGRAPH 13

By importing, offering to sell, selling and/or using those citalopram products, Forest Pharma has directly infringed, and is directly infringing, the '973 patent under 35 U.S.C. § 271(g).

ANSWER TO COMPLAINT PARAGRAPH 13

Denied.

COMPLAINT PARAGRAPH 14

On information and belief, Forest Pharma has and is actively inducing consumers to infringe the '973 patent under 35 U.S.C. § 271(b).

ANSWER TO COMPLAINT PARAGRAPH 14

Denied.

COMPLAINT PARAGRAPH 15

Upon information and belief, Forest Pharma's infringement of the '973 patent has been and continues to be willful and deliberate.

ANSWER TO COMPLAINT PARAGRAPH 15

Denied.

COMPLAINT PARAGRAPH 16

As a direct and proximate consequence of the acts and practices of Forest Pharma, Infosint has been, is being, and, unless such acts and practices are enjoined by the Court, will continue to be irreparably injured in its business and property rights, and has suffered, is suffering, and will continue to suffer injury and damages for which it is entitled to relief under 35 U.S.C. § 284.

ANSWER TO COMPLAINT PARAGRAPH 16

Denied.

COMPLAINT PARAGRAPH 17

Each of the preceding paragraphs 1 through 16 above, inclusive, is incorporated herein by reference.

ANSWER TO COMPLAINT PARAGRAPH 17

Defendant restates and incorporates by reference its responses to the averments contained in Complaint Paragraphs 1 through 16 as though fully set forth herein.

COMPLAINT PARAGRAPH 18

Defendant Forest Pharma has imported and is importing into the United States and/or has offered to sell, sold, or used and is offering to sell, selling and using within the United States, citalopram made by a process covered by one or more of the claims of the '516 patent

ANSWER TO COMPLAINT PARAGRAPH 18

Denied

COMPLAINT PARAGRAPH 19

By importing, offering to sell, selling and/or using those citalopram products, Forest Pharma has directly infringed, and is directly infringing the '516 patent under 35 U.S.C. § 271(g).

ANSWER TO COMPLAINT PARAGRAPH 19

Denied.

COMPLAINT PARAGRAPH 20

On information and belief, Forest Pharma has and is actively inducing consumers to infringe the '973 *[sic]* patent under 35 U.S.C. § 271(b).

ANSWER TO COMPLAINT PARAGRAPH 20

Denied.

COMPLAINT PARAGRAPH 21

Upon information and belief, the *[sic]* Forest Pharma's infringement of the '516 patent has been and continues to be willful and deliberate.

ANSWER TO COMPLAINT PARAGRAPH 21

Denied.

COMPLAINT PARAGRAPH 22

As a direct and proximate consequence of the acts and practices of defendants *[sic]*, Infosint has been, is being and, unless such acts and practices are enjoined by the Court, will continue to be irreparably injured in its business and property rights, and has suffered, is suffering, and will continue to suffer injury and damages for which it is entitled to relief under 35 U.S.C. § 284.

ANSWER TO COMPLAINT PARAGRAPH 22

Denied.

COMPLAINT PRAYER FOR RELIEF

WHEREFORE, Infosint prays for the entry of a judgment from this Court:

- a. Declaring that the '973 patent is valid and enforceable;
- b. Declaring that Forest Pharma has infringed the '973 patent;
- c. Declaring that Forest Pharma has willfully infringed the '973 patent;
- d. Declaring that the '516 patent is valid and enforceable;
- e. Declaring that Forest Pharma has infringed the '516 patent;
- f. Declaring that Forest Pharma has willfully infringed the '516 patent;
- g. Declaring that this is an exceptional case under 35 U.S.C. § 285;
- h. Awarding Infosint its reasonable attorney fees, expenses and costs in this action;
- i. Preliminarily and/or permanently enjoining Forest Pharma from infringing the '973 patent;
- j. Preliminarily and/or permanently enjoining Forest Pharma from infringing the '516 patent;
- k. Awarding Infosint damages in accordance with 35 U.S.C. §284;
- l. Awarding Infosint such other and further relief as this Court may deem to be just and proper.

ANSWER TO COMPLAINT PRAYER FOR RELIEF

Forest Pharma denies that Infosint is entitled to any relief whatsoever from Forest Pharma or the Court, either as prayed for in its Complaint or otherwise.

Forest Pharma further denies each allegation contained in Infosint's Complaint that was not specifically admitted, denied, or otherwise responded to in this Answer And Counterclaims.

DEFENSES

In further Answer to Infosint's Complaint, Forest Pharma hereby pleads and affirmatively sets forth the following defenses, undertaking the burden of proof on such defenses only to the extent required by law.

Failure To State A Claim Upon Which Relief Can Be Granted

23. Infosint's Complaint fails to state a claim against Forest Pharma upon which relief can be granted.

Noninfringement

24. Forest Pharma has not infringed any claim of U.S. Patent Nos. 6,458,973 ("the '973 patent") or 6,703,516 ("the '516 patent") directly, indirectly, literally, or under the doctrine of equivalents.

25. Forest Pharma has not induced or contributed to any direct, indirect, literal, or doctrine of equivalents infringement of any claim of the '973 patent or the '516 patent.

26. Forest Pharma has not infringed any claim of the '973 patent or the '516 patent under 35 U.S.C. § 271(g).

Invalidity Under Part II Of Title 35

27. Each asserted claim of the '973 and '516 patents is invalid for failure to comply with one or more of the conditions of patentability specified in part II of Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101, 102, and 103.

Unenforceability Due To Inequitable Conduct

28. Upon information and belief, the '973 and '561 patents are unenforceable due to inequitable conduct in their procurement.

29. Upon information and belief, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 engaged in inequitable conduct during the prosecution of the '973 patent before the United States Patent and Trademark Office ("USPTO"), rendering the '973 patent completely and permanently unenforceable, including the inequitable conduct described as follows.

a) Upon information and belief, during prosecution of the '973 patent, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 were aware of the prior invention of the subject matter claimed by the '973 patent by scientists at H. Lundbeck A/S and failed to disclose this highly material information to the USPTO. The failure to disclose this highly material information was knowing, willful, and done with the intent to deceive the USPTO into improperly issuing the '973 patent. As a result, the '973 patent is completely and permanently unenforceable.

b) Upon information and belief, during prosecution of the '973 patent, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 were aware of an inventorship dispute with H. Lundbeck A/S regarding subject matter claimed by the '973 patent and failed to disclose this highly material information to the USPTO. The failure to disclose this highly material information was knowing, willful, and done with the intent to deceive the USPTO into improperly issuing the '973 patent. As a result, the '973 patent is completely and permanently unenforceable.

c) Upon information and belief, during prosecution of the '973 patent, co-inventor Leone Dall' Asta filed a declaration with the USPTO dated December 19, 2001 that, *inter alia*, included false and misleading material information. This false and misleading material declaration was submitted to the USPTO knowingly, willfully, and with the intent to deceive the USPTO into improperly issuing the '973 patent. As a result, the '973 patent is completely and permanently unenforceable.

30. Upon information and belief, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 engaged in inequitable conduct during the prosecution of the '516 patent before the USPTO, rendering the '516 patent completely and permanently unenforceable, including the inequitable conduct described as follows.

a) Forest Pharma restates and incorporates by reference all of the allegations contained in Answer Paragraph 29. The '516 patent issued from a patent application that was a continuation of the patent application that led to the '973 patent and claims priority to that application. As set forth in Answer Paragraph 29, the '973 patent was obtained through inequitable conduct during the prosecution of that patent before the USPTO. This inequitable conduct taints the related '516 patent and renders the '516 patent completely and permanently unenforceable.

b) Upon information and belief, during the prosecution of the '516 patent, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 were aware of the prior invention of the subject matter claimed by the '516 patent by scientists at H. Lundbeck A/S and failed to disclose this highly material information to the USPTO. The failure to disclose this highly material information was knowing, willful, and done

with the intent to deceive the USPTO into improperly issuing the '516 patent. As a result, the '516 patent is completely and permanently unenforceable.

c) Upon information and belief, during prosecution of the '516 patent, one or more of the named inventors and/or other individuals subject to the requirements of 37 C.F.R. 1.56 were aware of an inventorship dispute with H. Lundbeck A/S regarding subject matter claimed by the '516 patent and failed to disclose this highly material information to the USPTO. The failure to disclose this highly material information was knowing, willful, and done with the intent to deceive the USPTO into improperly issuing the '516 patent. As a result, the '516 patent is completely and permanently unenforceable.

License

31. Infosint's claims are barred in whole or in part by a license to practice the '973 and '516 patents.

32. An express license to practice the '973 and '516 patents is contained in the Agreement On Purchase Of IP-Rights dated October 6, 1999 between H. Lundbeck A/S and one of Infosint's predecessors-in-interest, Syrio SA.

33. To the extent that an express license to practice the '973 and '516 patents is somehow not found in the October 6, 1999 agreement identified in Answer Paragraph 32, an implied license to practice the '973 and '516 patents exists based on that agreement and/or the parties' and/or their predecessors' conduct and dealing in connection with the negotiation and execution of, and/or performance under, that agreement.

Unenforceability Due To Patent Misuse

34. Each asserted claim of the '973 and '516 patents is unenforceable due to patent misuse.

35. Upon information and belief, at the time of filing its Complaint in this action, Infosint knew or should have known that the '973 and '516 patents were not infringed and/or invalid under, *inter alia*, 35 U.S.C. §102(g)(1). Upon information and belief, at the time of filing its Complaint in this action, Infosint knew or should have known that the '973 and '516 patents had been obtained through inequitable conduct before the USPTO and were, therefore, completely and permanently unenforceable. Infosint's conduct in filing its Complaint in this action constitutes misuse of the '973 and '516 patents and renders those patents completely unenforceable against Forest Pharma.

Arbitration And Award

36. Infosint's claims are barred in whole or in part by the prior arbitration between Infosint's predecessors-in-interest, Syrio S.A. and Norpharma S.p.A., and H. Lundbeck A/S and the payment of the March 7, 2005 award in that arbitration regarding the license agreement identified in Answer Paragraph 32.

Laches

37. Even if an asserted claim of the '973 patent or '516 patent is somehow found not invalid and unenforceable, and even if Forest Pharma is somehow found to infringe any such claim, any such infringement that occurred before April 12, 2006 cannot be the subject of any damages award in this action under the doctrine of laches.

Estoppel

38. Even if an asserted claim of the '973 patent or '516 patent is somehow found not invalid and unenforceable, and even if Forest Pharma is somehow found to infringe any such claim, any such infringement cannot be the subject of any damages award in this action under the doctrine of estoppel.

35 U.S.C. § 287(b)

39. Even if an asserted claim of the '973 patent or '516 patent is somehow found not invalid and unenforceable, and even if Forest Pharma is somehow found to infringe any such claim, pursuant to 35 U.S.C. § 287(b), Infosint is not entitled to any remedy for infringement under 35 U.S.C. § 271(g) before Forest Pharma had notice of that infringement.

Collateral Estoppel

40. Infosint is collaterally estopped from asserting the '516 patent due to, *inter alia*, counsel for Infosint's representation that Infosint would not be asserting the '516 patent with respect to patents and processes to date. *See* Ex. A.

Forest Pharma reserves the right to assert additional defenses to Infosint's claims as they become known or apparent. Forest Pharma further reserves the right to adopt and rely upon any defenses asserted by any subsequent parties to this proceeding.

COUNTERCLAIMS

Forest Pharma, for its counterclaims against Infosint S.A., hereby alleges as follows:

COUNT I

Counterclaim For A Declaratory Judgment Of Patent Noninfringement, Invalidity, And Unenforceability Of The '973 Patent

Defendant and Counterclaim Plaintiff Forest Pharmaceuticals, Inc. ("Forest Pharma"), in counterclaim against Plaintiff and Counterclaim Defendant Infosint S.A. ("Infosint"), hereby alleges and avers as follows:

1. This is a counterclaim for a declaratory judgment of noninfringement, invalidity, and unenforceability of all of the asserted claims of U.S. Patent No. 6,458,973 ("the '973 patent"). This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*
2. Counterclaim Plaintiff Forest Pharma is a Delaware corporation, having a principal place of business at 13600 Shoreline Drive, Earth City, Missouri.
3. Upon information and belief, Counterclaim Defendant Infosint S.A. is a Swiss Corporation having a principal place of business at Via Cantonale 658a, P.O. Box 83, CH-7745 Poschiavo, Li Curt, Switzerland.
4. This Court has subject matter jurisdiction over this Counterclaim pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and 28 U.S.C. §§ 1331 and 1338(a).
5. Infosint is subject to personal jurisdiction in this Court, as evidenced by, *inter alia*, its consent to jurisdiction in this Court.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(d).

7. As demonstrated by the Complaint filed by Infosint in this action, and Forest Pharma's Answer And Counterclaims to that Complaint, an actual and justiciable controversy exists between Infosint and Forest Pharma regarding the noninfringement, invalidity, and unenforceability of the '973 patent.

8. Forest Pharma restates and incorporates by reference Answer Paragraphs 23 through 40 as though fully set forth herein.

9. A judicial declaration that the '973 patent is invalid, unenforceable, and not infringed is necessary and appropriate to resolve this controversy.

COUNT II

Counterclaim For A Declaratory Judgment Of Patent Noninfringement, Invalidity, And Unenforceability Of The '516 Patent

Defendant and Counterclaim Plaintiff Forest Pharmaceuticals, Inc. ("Forest Pharma"), in counterclaim against Plaintiff and Counterclaim Defendant Infosint S.A. ("Infosint"), hereby alleges and avers as follows:

10. This is a counterclaim for a declaratory judgment of noninfringement, invalidity, and unenforceability of all of the asserted claims of U.S. Patent No. 6,703,516 ("the '516 patent"). This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

11. Forest Pharma restates and incorporates by reference Counterclaim Paragraphs 2 through 6 as though fully set forth herein.

12. As demonstrated by the Complaint filed by Infosint in this action, and Forest Pharma's Answer And Counterclaims to that Complaint, an actual and justiciable controversy exists between Infosint and Forest Pharma regarding the noninfringement, invalidity, and unenforceability of the '516 patent.

13. Forest Pharma restates and incorporates by reference Answer Paragraphs 23 through 40 as though fully set forth herein.

14. A judicial declaration that the '516 patent is invalid, unenforceable and not infringed is necessary and appropriate to resolve this controversy.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counterclaim Plaintiff Forest Pharmaceuticals, Inc. prays for entry of judgment:

A. Dismissing Infosint's Complaint, and all the claims therein, with prejudice;

B. Declaring that Forest Pharmaceuticals, Inc. has not infringed, or induced or contributed to any infringement of, any claim of U.S. Patent Nos. 6,458,973 and/or 6,703,516;

C. Declaring that each asserted claim of U.S. Patent Nos. 6,458,973 and 6,703,516 is invalid;

D. Declaring that each asserted claim of U.S. Patent Nos. 6,458,973 and 6,703,516 is unenforceable;

E. Declaring this case to be exceptional within the meaning of 35 U.S.C. § 285 and awarding Forest Pharma the attorney fees, costs and expenses that it incurs in this action; and

F. Awarding Forest Pharma such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Forest Pharma hereby demands a trial by jury for all the issues so triable.

Dated: August 8, 2007

By:

/s/ Peter J. Armenio
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